

# Prognosis – February 8, 2012

## DEN1014 Clinical Epidemiology

# Prognosis

	Qualitative	Cross-Sectional	Case Control	Cohort	RCT
Diagnosis				☆	☆☆
Therapy				☆	☆☆
Prognosis				☆☆☆	
Screening			☆	☆	☆☆
Views/beliefs perceptions	☆☆☆				
Prevalence/hypothesis generation	☆☆☆	☆☆☆			

- An inception cohort of persons, all initially free of the outcome of interest
- Follow-up of at least 80 per cent of patients until the occurrence of either a major study criteria or the end of the study
- A statistical analysis consistent with the study design.

# Are the results of the trial valid?

## Primary guides

### 1. ...similar point in the course of the disease

- Prospective
- Retrospective
  - Recall long after a treatment will probably be skewed regarding problems that may have occurred due to the treatment, especially if developed in an early phase following treatment
  - Case-control studies

# Sufficiently long and complete follow-up?

1. What is a reasonable follow-up period?  
1 Year? 3 years? 5 years?

Long follow-up ---> drop-outs

Category A: Some drop-outs cannot be avoided, but have no association with prognosis

- Address change, disease due to reasons not related to intervention, death, etc
- Do not cause concern, especially if the number is small

# Sufficiently long and complete follow-up?

Category B: Drop-outs due to other reasons: disease, age, reluctance to continue to be recalled, dissatisfaction with services, etc

- Inadequate description of the proportion of drop-outs – with a description of the treatment outcome in this group – reduces the validity of the study
- Two strategies can be applied when appraising the data
  - Sensitivity analysis
  - 5% and 20% rule

# Sensitivity analysis - "What if?"

- Example: 100 endos: 25 patients drop-out and 10 flare-ups amongst the 75
- Success =  $100\% - 10/75 = 87\%$
- What about the 25 lost patients?
- Worst-case scenario: all the lost 25 patients had flare-ups -> "success" is  $100\% - ((25+10)/(25+75)) = 65\%$
- Best-case scenario: none of the 25 patients had flare-ups -> "success" is  $100\% - ((0+10)/(25+75)) = 90\%$
- Hence, the success is somewhere between 65-90%

# Sensitivity analysis - "5 and 20" rule

- Less than 5% drop-out can be ignored
- More than 20% drop-out raises concern about the study's validity
- The percentages are suggestive and have to be viewed in context with the incidence of technical and clinical problems

# The Effects of a High Proportion of Drop-Outs on Interpretation

- Depends on the incidence of adverse events
- Low incidence: Strong effect of a moderate drop-out proportion
- High incidence: Less effect of moderate drop-out proportion



### 3. Objective and Unbiased Outcome

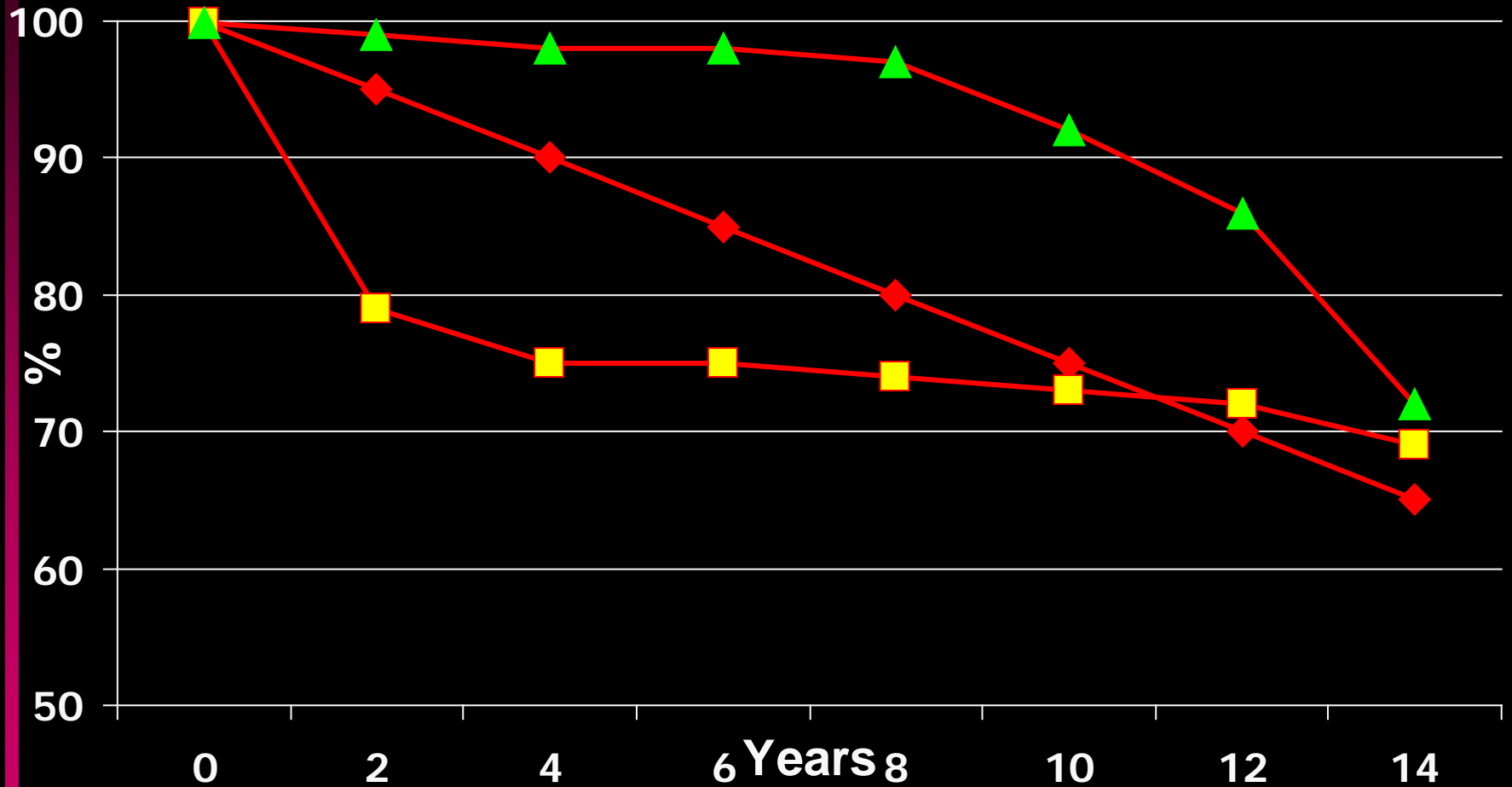
Choice of criteria - What are the most relevant in your clinical discipline? E.g., for restorative:

- The quality of the remaining dentition
  - Secondary caries, endodontic complications, etc.
- To what capacity stomatognathic functions are maintained or reestablished
- Subjective patient opinions such as e.g. esthetics, function and comfort
- Various criteria for describing the morphology of a prosthesis as measures of treatment “quality” or success?
- ---Surrogate outcomes very often used ----

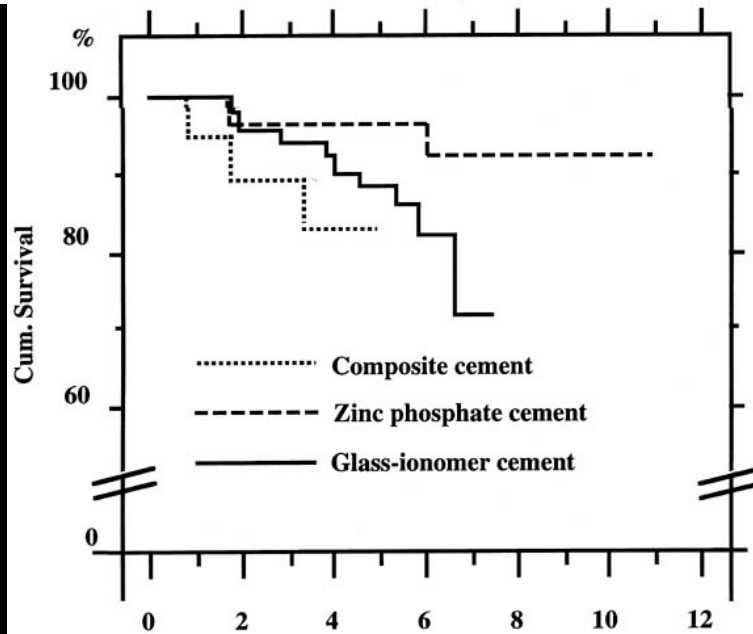
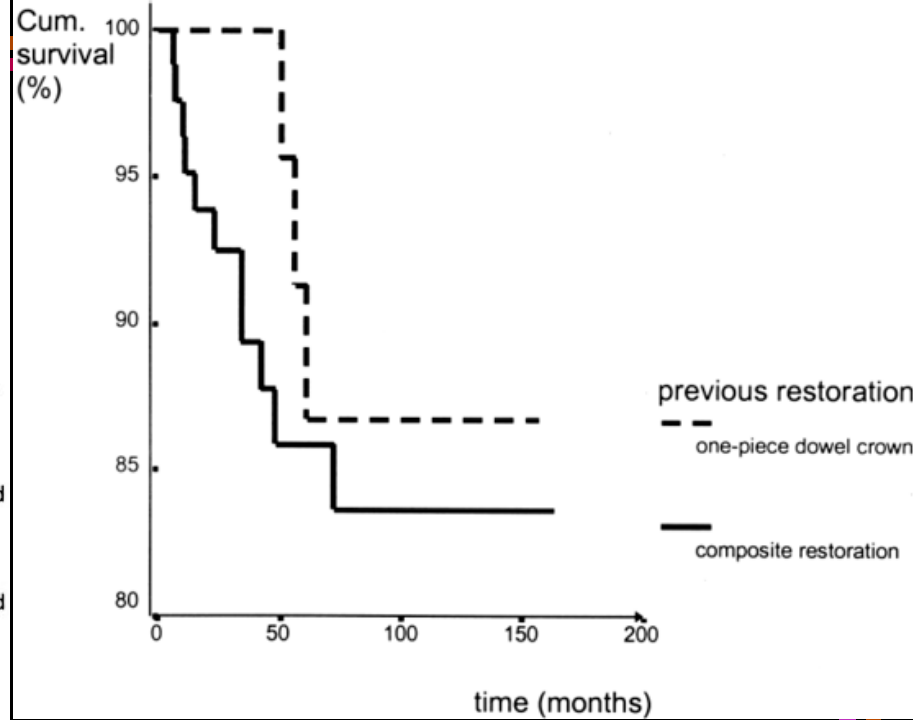
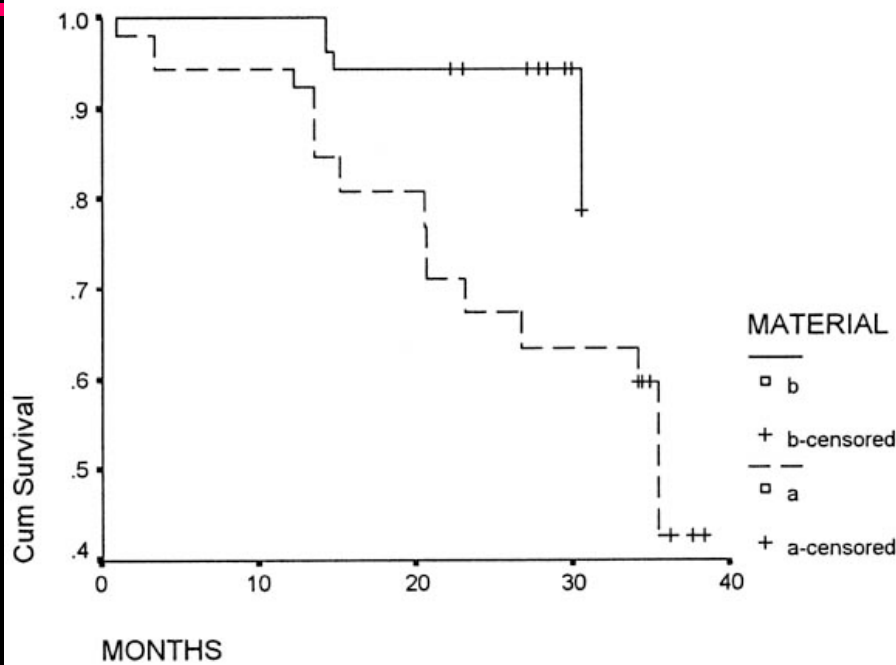
# Prognosis – likelihood estimates

- Proportion of survival or success according to some specific criteria after a given temporal interval, e.g. after 1 or 5 years
- Median time of survival (in years), where 50% of the study unit, e.g. the patient, prosthesis, restorations or tooth, have failed, or
- Survival curves – describe for each time unit along a horizontal axis estimates of the proportion of the study unit that remain intact according to survival or success according to some specific criteria

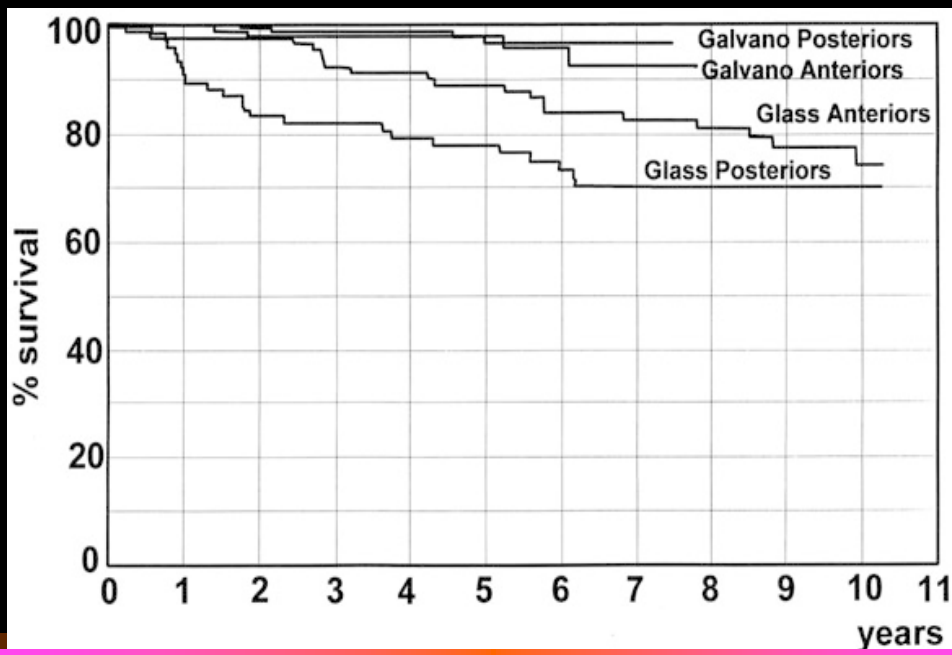
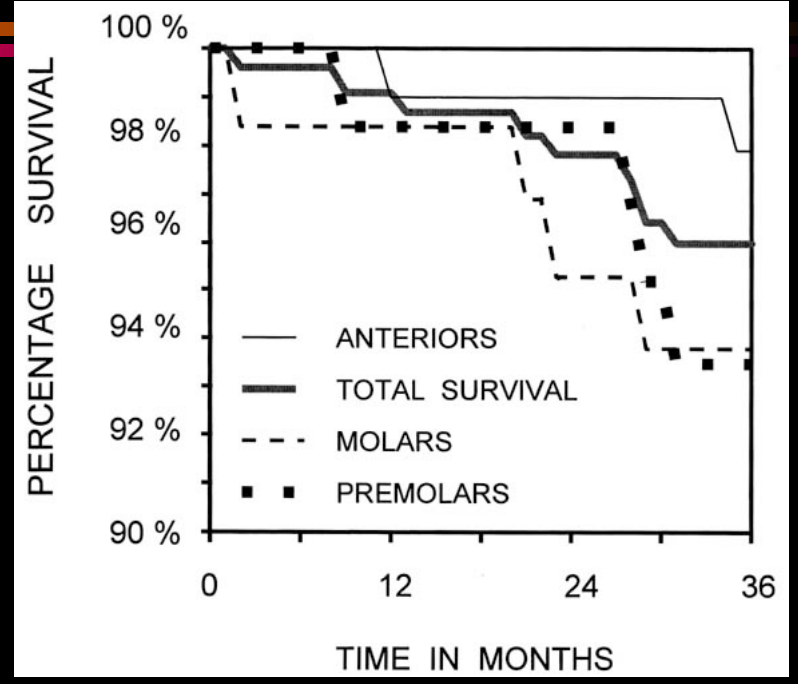
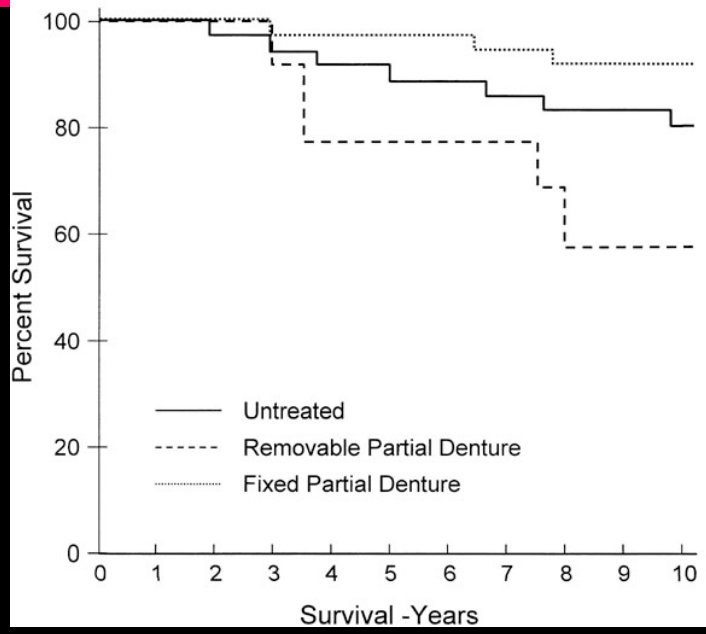
# Survival Curves

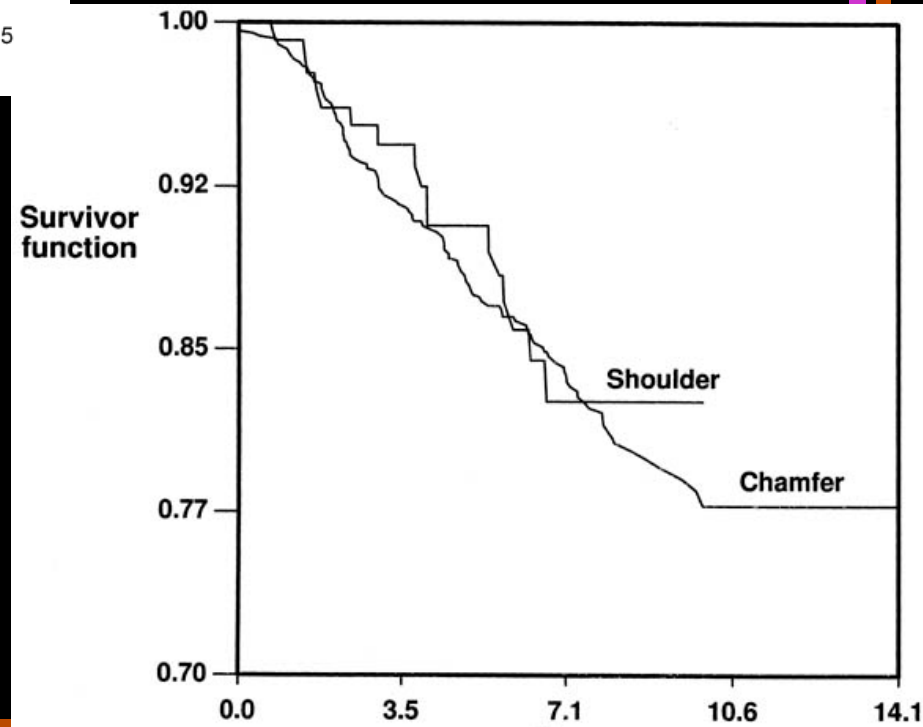
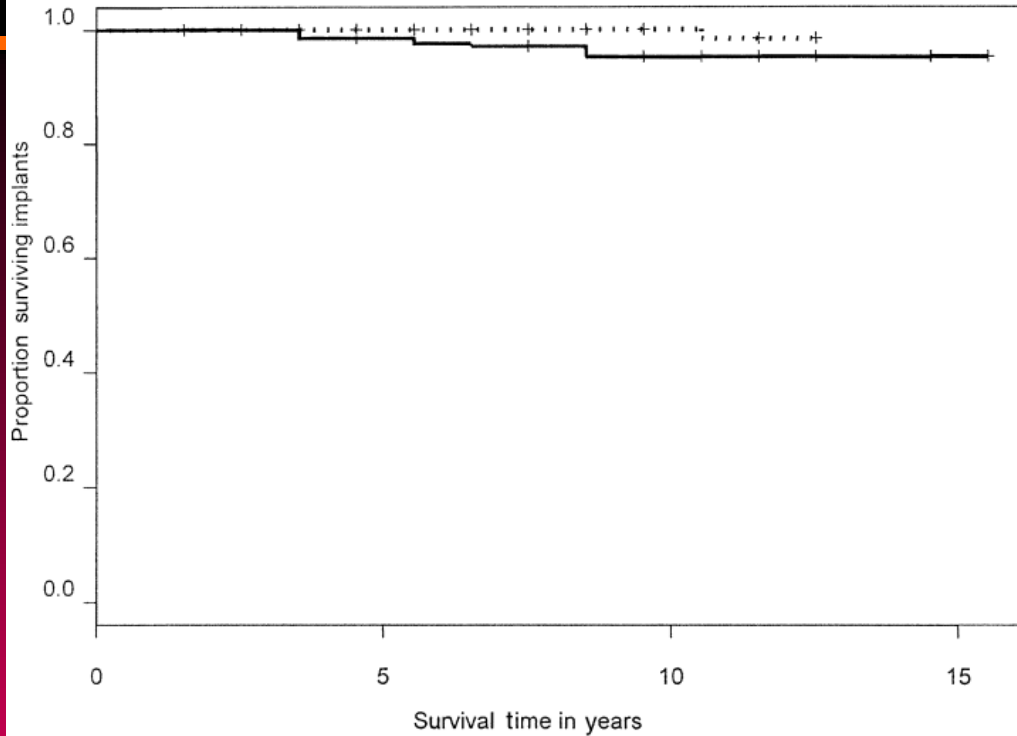


# Survival Functions



Kaplan-Meier Survival Curve for the Three Treatment Categories

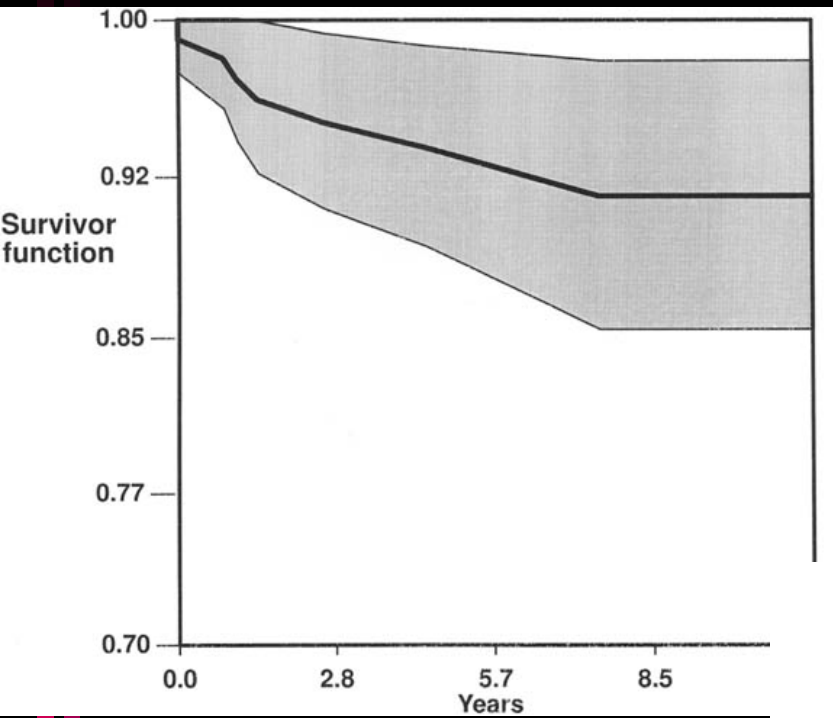




## 6. How precise are the estimates of likelihood?

- All good clinical prognosis studies include measures of confidence intervals for prognosis-estimates
- A 95% confidence interval consists of two values that indicating an interval where we can be 95% certain that the true value lies
- A narrow confidence interval is an indication of a precise estimate of the true value

# Sample size and confidence interval



Alternative 1 - shade

Alternative 2 - bars

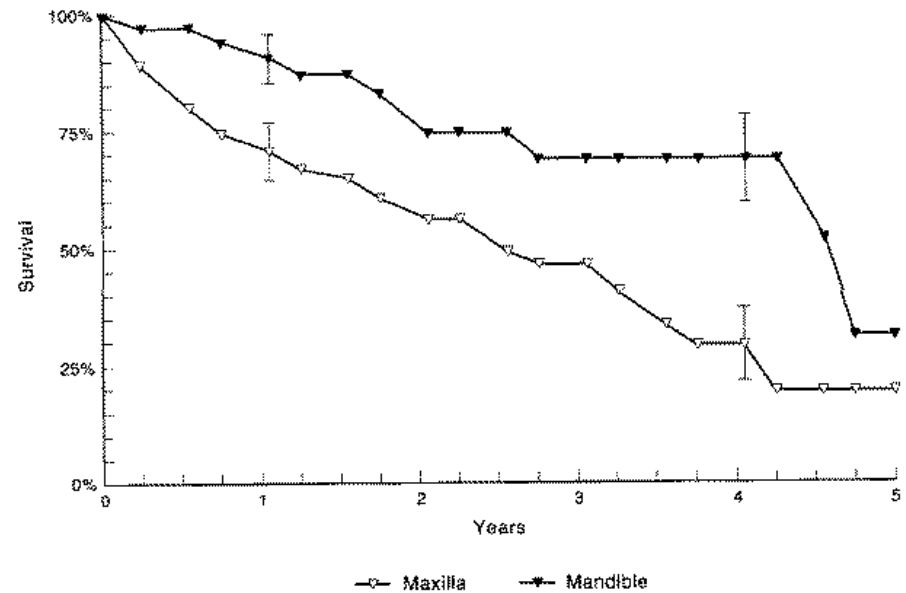


Fig. 1. Survival curves ( $S_t$ ) of maxillary ( $n = 34$ ) and mandibular ( $n = 56$ ) 'replacement' posterior resin-bonded bridges (Kaplan-Meier).



## 7. Application to own patients?

- Usually simple question
- Seldom biological rationale
- Special patient groups, e.g. xerostomia, high caries-activity, aggressive periodontitis, bruxism, hockeyplayers...

## 8. Attitudes to risk differ!

<b>VALIDITY: Are the results of this prognosis study valid?</b>	<b>A</b>	<b>B</b>	<b>C</b>
<b>1 Was a defined, representative sample of patients assembled at a common point in the course of the disease?</b>	<b>Yes</b>	<b>Can't tell</b>	<b>No</b>
<ul style="list-style-type: none"><li>• - <i>inclusion criteria of sample</i></li><li>• - <i>sample selection explained</i></li><li>• - <i>adequate description of diagnostic criteria</i></li><li>• - <i>clinical and demographic characteristics described</i></li></ul>			

Gilbert GH, Shelton BJ, Chavers LS, Bradford EH Jr. Predicting tooth loss during a population-based study: role of attachment level in the presence of other dental conditions. J Periodontol. 2002 Dec;73(12):1427-36.

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• <i>Fully defined prognostic variables</i>	<b>Yes</b>	<b>Can't tell</b>	<b>No</b>
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**IMPORTANCE What are the results?**

- How likely are outcome event(s) over a specified period?
- How precise are the estimates of these outcomes?

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- How likely are outcome event(s) over a specified period?			
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<b>APPLICABILITY Will the results help locally?</b>			
5. Were the study patients similar to my own?			
• <i>Do you think that the patients covered by the trial are similar enough to your patient population?</i>	<b>Yes</b>	<b>Can't tell</b>	<b>No</b>

**A**                      **B**                      **C**

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**Yes**                      **Can't tell**                      **No**





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